BD Medical Systems
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K021475

JUL 19 2002

BD
Indispensable to human health

Summary of Safety and Effectiveness

Change to the Formulation of the Lube Carrier for Needle Products

1 BD Contact person:
Pasquale Amato
Regulatory Affairs Coordinator
BD Medical Surgical – Mail Code 226
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Phone (201) 847-4513
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2 Device Name: BD Single Lumen Needle, Syringe and Blood Collection Set

3 Predicate Device(s):

Predicate Devices	510(k) Number
BD Hypodermic Needles	Pre-Amendment
BD Ultra Fine II, Micro Fine + Short Needle Insulin	K955235
BD Intravascular Catheters	K013073
BD Pen Needles	K002938; K970737; K950466
BD Introcyte Introducers	K013304
Eclipse Safety Needle	K982541
SafetyGlide Needle	K951254
Blood Collection Syringe	K982922
Safety-Lok Blood Collection Set	K931367 K965202 K972404 K980414
Passive Shielding Blood Collection Needle	K003461
Push Button Blood Collection Set	K011984

4 Product Description / Function:
This change in needle lubricant carrier is across the BD product lines.

5 Intended Uses: These needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.

6 Comparison of Modified and Predicate Device:

The table provides a comparison of the single lumen needles, insulin syringes and blood collection set with the predicate devices:

Element of Comparison	Single lumen needles, insulin syringes and blood collection set	Similarity to Predicate Devices
Intended Use	These needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection	Predicate devices identical
Sterility	Sterile fluid path	Predicate devices identical
Sterilization	Gamma or EtO. Remains unchanged	Predicate devices identical
Design	Design remains unchanged	Predicate devices identical
Needle Material	Needle materials remain unchanged	Predicate devices identical
Packaging	Packaging remains unchanged	Predicate devices identical

7 Equivalence determination:
Single lumen needles, insulin syringes and blood collection sets are being compared to themselves. The indications for use, components, silicone proportions in the lubricants, labeling, performance and product claims remain the same. The only product modification is in the carrier used to disperse the silicone. Since the carrier evaporates, leaving only the silicone on the device, the modified devices are substantially equivalent to the currently marketed devices.

Intended uses: These needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.

Materials: The needle materials remain unchanged. Predicate device is identical.

Physical, Mechanical, and Biological Specifications: These specifications are unaffected by the lubricant carrier formulation change and the predicate device are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2002

Mr. Pasquale Amato
Regulatory Affairs Coordinator
BD Medical Surgical
1 Becton Drive MC 226
Franklin Lakes, New Jersey 07417

Re: K021475
Trade/Device Name: BD Single Lumen Needle, Syringe and Blood Collection Set
Regulation Number: 880.5570, 880.5860 and 862.1675
Regulation Name: Hypodermic Single Lumen Needle, Piston Syringe and Blood Specimen Collection Device
Regulatory Class: II
Product Code: FMF, FMI and JKA
Dated: May 6, 2002
Received: May 8, 2002

Dear Mr. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K021475

Device Name: BD Single Lumen Needle, Syringe and Blood Collection Set

Indications for Use:

The needles are intended for general purpose fluid injection/aspiration, infusion, venipuncture to obtain blood collection and insulin injection.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ✓ Insulin Syringes/Needles
(Per 21 CFR 801.109)

Patricia Cusenza

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021475